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CONTROL OF VENEREAL DISEASES.

One million dollars will be expended by the Federal Government through the State boards of health in venereal-disease control during the fiscal year ending June 30, 1919. This sum is made available for expenditure, under regulations established by the Secretary of the Treasury, by an act of Congress approved July 9, 1918. An officer of the Public Health Service will have general charge of the work in each State in cooperation with the State health officer. The activities will be the following:

(*a*) Securing of reports of venereal infections.

(*b*) Control of those infected, so as to prevent further spread of the diseases.

(*c*) Establishment of free venereal clinics.

(*d*) Suppression of vicious conditions which favor the spread of venereal infections.

(*e*) Carrying out of systematic educational program for the general public as well as for those who are infected.

The act gives authority for a new division in the Bureau of the Public Health Service, to be called the Division of Venereal Diseases. Such a division has been organized and a chief appointed.[1]

The act also grants authority to the Public Health Service for the regulation of the interstate travel of venereally infected persons. The regulations are in course of preparation.

OFFICIAL CONTROL OF ANTIPNEUMOCOCCUS AND ANTI-MENINGOCOCCUS SERUMS.

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The Secretary of the Treasury is charged by law with the supervision over such prophylactic and therapeutic serums and vaccines as are sold in interstate commerce for human use. Under this law, United States standards have been adopted for diphtheria antitoxin

[1] The venereal control work begun a few months ago by the Public Health Service through the Division of Domestic Quarantine has been taken over by the new division.

and tetanus antitoxin. These standards are commonly used by the allies of the United States as well as in this country. No standards of potency for other serums had been adopted because it was not felt until recently that the methods of comparing other serums as regards their curative power had passed beyond the experimental stage. Indeed, an opinion as to whether the greater part of the other serums in use are of any value at all would be open to question; it is primarily the antitoxic serums from which benefit is to be expected. Within recent years, by the use of more direct methods of application, the intravenous and the intraspinal routes, antipneumococcic serum and antimeningococcic serum have given clinical evidence of potency. Difficulties in the standardization of these agents have led to the necessity for a method of control somewhat different from that required in relation to the two antitoxins. Tests for potency of the two serums do not always give definite results, and in addition, in the case of antimeningococcic serum, there is difference of opinion as to what particular method of testing is most useful. These facts, together with unfavorable criticisms of the serums to be had in trade channels, led to the authorization for the testing at the Hygienic Laboratory of the United States Public Health Service, of all lots of each of these preparations made for sale in interstate traffic, and the requirement that all lots pass this test satisfactorily before being released for sale.

A summary of the results of this method of guarding against products of poor quality, and some considerations in connection with the testing, are presented here.

Antipneumococcic Serum.

It has been shown that pneumococci may be divided into several groups; in the case of one of these, Group I, the antiserum prepared by the immunization of horses appears to have therapeutic value. This Group I antiserum is manufactured by several commercial firms and by at least three institutions not engaged in selling the serum.

Serological tests, particularly agglutination tests, have been used to some extent in estimating the potency of the serum, but they are regarded as not trustworthy, and the only test which need be considered is that which is based on the power of the serum to protect mice against amounts of a virulent culture many times as large as that required to kill control mice. Irregularity of results is often encountered in carrying out this test. This need not occasion surprise, as we depend on the use of a living microorganism the virulence of which varies with different cultures of the same strain, with the same culture at different periods of growth or storage, and with other circumstances. Thus, it sometimes happens that a mouse

receiving one dose of the culture will perish, while mice given an amount twice or even 10 times as large survive. This may occur in the control series of mice receiving the culture alone, or in a series protected by any of the serums tested. In other words, there is a very large factor of error inherent in the test itself; with only one mouse inoculated for each dose this error may be so large as to nullify the value of the test. It was found that such variations of the test as simultaneous or separate injection of serum and culture, the addition of a preservative to the culture, and excessive virulence of the microorganism, did not make any material difference in the results.

Serums claiming to be potent against Groups I, II, and III pneumococci are tested at the Hygienic Laboratory for protection against type I only, since there is not at present acceptable evidence of the therapeutic value of serums directed against infections with the other types of pneumococcus. Manufacturers of serums directed against Groups II and III employ appropriate protection tests for these groups.

Under this method of control, among 142 serums examined, 16 (11 per cent) have been rejected as below the potency considered desirable for a product for therapeutic use. The 126 other specimens have shown a degree of protection equivalent to, or higher than, a preparation made by a noncommercial laboratory which was reported to have given good results in its clinical applications.

Antimeningococcic Serum.

Various students of the meningococcus have divided the cultures of the organism isolated from the spinal fluid in cases of epidemic cerebrospinal meningitis into two, three, or four groups. We have not sufficient data to accept any of these groupings as final—indeed this subject is under very active investigation at the present time—but tentatively it seemed wise to accept for testing purposes a classification which recognizes four groups. The commercial serums are tested against one or more representatives of the four groups and are not passed for use unless there is definite evidence of antibodies against the four groups of meningococci and in a reasonably high titre for at least three of these groups.

There is no agreement as to a method of testing antimeningococcic serum which will give a result that may be regarded as a trustworthy guide to the probable therapeutic efficiency of the serum. At least four methods have been proposed for estimating the usefulness of this preparation in the treatment of meningitis, but no one of these has been proved to be superior to the others. The methods that have been employed are: Determination of the bacteriotropin content, of the agglutinin titre, of the complement fixation titre, and of the protection of animals from the effects of a virulent culture or the

toxic products of such a culture. Two of these tests at present command the support of the majority of workers on the subject: That which determines the agglutinating titre of the serum, and that which determines the complement fixation titre. Unless these tests are most carefully performed and adequately controlled, misleading results are likely to be obtained. Materials (antigens) for use in these tests, and instructions as to the details of performing the titrations, are supplied by the Hygienic Laboratory.

It has been found that among 161 commercial samples submitted, 39 (24 per cent) have failed to show a sufficiently high agglutinating titre or complement-fixing titre to justify passing the preparations for human use. As the serums are tested after having passed the manufacturers' tests, such a control as is being exercised is considered to be amply justified.

Summary.

It is thus seen that these special methods of control over antipneumococcic serum are used because the test for potency, though apparently a measure of its therapeutic value, is inaccurate, involving a large factor of error. Special methods of control over antimeningococcic serum are also used because of the difficulty in duplicating a given test in different laboratories and because of a lack of agreement as to the test which is most satisfactory.

Work now in progress is expected to result in the adoption of test serums which manufacturers may use for comparative testing. It seems unlikely that the same exactness that obtains in testing diphtheria antitoxin or tetanus antitoxin will be accomplished with antipneumococcic or antimeningococcic serum; but the user may be assured that either of these preparations, on leaving the manufacturing establishment, is of as high a degree of potency as it is practicable to attain. The regulations of the Treasury Department prohibit the dating of these serums beyond six months after manufacture or after removal from the manufacturer's cold storage. Hence there should be no marked deterioration of the preparation while on the market.